

Office Action Response
U.S.S.N. 10/073,682
Page No. 12 of 18

REMARKS

The present invention is directed to a shred resistant, ultra-high molecular weight polyethylene, micromesh interproximal device produced by fibrillating and slitting stretched polyethylene film having a tensile-strength from between about 0.7 GPa and about 5GPa, where said polyethylene has an intrinsic viscosity of from between about 5 and about 50 dl/g and wherein said resultant micromesh tape is coated with an oral care substance at from between about 10 and about 120 mg/yd.

Claim Rejections - 35 U.S.C. § 112

Claims 3, 7, 8, 15, 16, 21 and 22 are rejected under Section 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendments made to these claims, this rejection should be reconsidered and withdrawn. Such action is respectfully requested. Specifically:

Claim 3 recites that the device is fibrillating as described as illustrated in Figs. 5 and 6. This claim has been amended to recite the nature of the fibrillating apparatus as described in the application as filed, namely:

Fig. 5 is an example of a **tapping screw-like fibrillator** which is hexagonal in shape with 15-35 screw threads per inch; and

Fig. 6 is an example of a **file-like fibrillator** having a rough surface similar to the surface of a round file in combination with spiral grooves.

Claims 7, 15, 16, 21 and 22 contain the trademark/trade names SoftAbrasivesTM, MICRODENT®, ULTRAMULSION®. The trademarks have been replaced by the

Office Action Response
U.S.S.N. 10/073,682
Page No. 13 of 18

generic terminology that each mark represents. No new matter has been added by these amendments.

Claims 7 and 8 recites the limitation "mixtures of (a) and (b)" in line 19, and line 9 respectively. Proper antecedent basis has bee provided.

Claim Rejections - 35 U.S.C. § 103

Claims 1-22 are rejected under Section 103(a) as being unpatentable over the combined disclosures of Zachariades et al (US 5,479,952) and Hill et al (US 5,098,711). This rejection is respectfully traversed for the following reasons:

The Examiner has broadly characterized the claims of the present invention as being drawn to "an interproximal device comprising ultra high molecular weight polyethylene (UHMWPE) and a coating." While Applicant appreciates the characterization, it misses several key characteristics of both the UHMWPE and the coating being claimed herein, which differentiates the present invention from the teachings of the cited prior art, namely:

As defined by Claim 1, the present invention is a two part invention, namely; I - the UHMWPE tape material and II - a coating; but the details include:

I. An ultra-high molecular weight polyethylene film having specific physical properties, including:

- (1) a tensile strength from between about 0.7 GPa and about 5 GPa;
- (2) an intrinsic viscosity from between about 5 and about 50 db/g;

Office Action Response

U.S.S.N. 10/073,682

Page No. 14 of 18

- (3) the material has been stretched, fibrillated and slit into a **micromesh tape** suitable for use as an interproximal device having further properties, namely:
 - (a) the tape has a fibrillation density from between about 5% and about 90% of the total tape surface,
 - (b) the tape has a width from between about 0.035 and about 0.12 inches,
 - (c) the tape has a thickness from between about 0.001 and about 0.004 inches, and
 - (d) the tape has a denier from between about 200 and about 600;
 - (e) the tape is shred resistant; and
 - (f) the tape provides an entrapment factor of at least two.

and

II. A coating for the micromesh tape which has these characteristics:

- (1) the coating comprises an oral care substance at from between about 10 and about 120 mg/yd; and
- (2) the coating is released from the micromesh tape during flossing.

Each of these factors is recited in Claim 1 and this combination of physical properties of "micromesh tape" is neither taught nor suggested by the material of the cited art, particularly, Zachariades.

Zachariades (US 5,479,952) teaches a dental floss comprised of a **unitary filament** of high molecular weight polyethylene material having a molecular weight of at least 300,000, a Young's modulus in the range of 0.5 GPa to 10 GPa and a tensile strength of 0.1 GPa to 1.2 GPa. (See Claim 1.)

Office Action Response
U.S.S.N. 10/073,682
Page No. 15 of 18

What is a "unitary filament"? The '952 patent specification provides no definition for this term. The dictionary (Webster's Ninth New Collegiate – 1989) defines -- unitary -- as "undivided or whole" and -- filament -- as "a single thread or a thin flexible threadlike object". Thus, a -- unitary filament -- would be a "one-piece thread or a one-piece thin flexible threadlike object". The material defined by Claim 1 of the '952 patent is likely being distinguished from traditional multifilament dental floss.

The presently claimed micromesh tape is neither a multifilament dental floss nor is it a unitary filament. Instead it is a "mesh product" formed when the UHMWPE material is stretched, fibrillated and/or slit to a fibrillation density from between about 5% and about 90% of the total tape surface.

Additional testing of the micromesh tape defined by Claim 1 of the present invention has shown that a tape having about 350 denier, from about 0.001 to about 0.0014 inches thick, with low to moderate fibrillation, has a Young's modulus of about 68 GPa, which clearly places micromesh outside the Young's modulus range set out in Claim 1 of Zachariades, i.e. "0.5 GPa to 10 GPa."

The Zachariades specification teaches other specific Young's modulus levels for various high molecular weight products as summarized below:

Example No.	Product	Young's modulus (in GPa)
1	DENTAL FLOSS	0.5 to 10
2	FISHING LINE	--
3	HIGH MOLECULAR WEIGHT POLYETHYLENE TAPE	at least 55
4	POWDER COMPACTED POLYETHYLENE	12

Office Action Response
 U.S.S.N. 10/073,682
 Page No. 16 of 18

5	FIBROUS TAPE	hot rolled – 2.8 after hot – 68
6	POLYPROPYLENE TAPE	at least 3
7	HIGH DENSITY POLYETHYLENE	at least 32
7(a)	HIGH DENSITY POLYETHYLENE	at least 3

Clearly, Zachariades neither teaches nor suggests the base material of the present invention – namely what Applicant calls – “micromesh” tape. Zachariades teaches and claims a “unitary filament.” The two are not the same – particularly given the differences in physical properties such as Young’s modulus. The addition of the Hill teachings does not change this fact.

Hill discloses a method of treating the oral cavity for the improved removal of plaque, through the use of a multifilament dental floss, said floss containing a cleaning preparation comprising a surfactant and a coating substance at from between 5 and about 100% by weight of the weight of the floss strands, and optionally further containing up to about 50% by weight of an active chemotherapeutic agent selected from the group consisting of antimicrobials, antibiotics, antioxidants, desensitizers, and anti-tartar agents.

The proposed combination of Zachariades and Hill is not proper, given that Zachariades teaches a monofilament product (unitary filament) and Hill teaches coatings deemed suitable for multifilament dental flosses. Hill clearly teaches multi-strand (not monofilament) dental floss containing, an ingestible, nonfoaming, plaque disrupting composition comprising cleaners and coating substances dispersible in said cleaners wherein:

- a. the multi-strand floss:
- 1. contains from between 2 and 12 strands,

Office Action Response
U.S.S.N. 10/073,682
Page No. 17 of 18

2. has a denier between about 300 and about 12,000, and
3. contains between about 100 and about 800 filaments;
 - b. the strands include natural and/or synthetic fibers and mixtures thereof including cotton, silk, polyester and nylon; and
 - c. cleaning agents as specified therein.

Nothing in Hill teaches coating ingredients for monofilament dental flosses. The coating agents taught therein might be "obvious to try" with monofilament flosses, but that does not make them obvious under the requirements of Section 103. The Hill teachings are specifically based upon "loading" the coating ingredients within the spaces of the multi-fibers comprising the floss. Zachariades teaches UHMWPE floss made with a unitary filament (monofilament) structure, not a multi-fiber floss.

Accordingly, the Section 103 rejection should be reconsidered and withdrawn.
Such action is respectfully requested.

Allowable Subject Matter

Applicant appreciates the notification that Claims 18 and 19 would be allowed if placed in independent form including all of the limitations of the base claim and any intervening claims. Such amendments are not believed to be necessary at this time, as it is believed that the claims from which these claims depend are likewise allowable in view of the amendments and remarks made herein.

TIME EXTENSION PETITION

Applicant hereby petitions for a one-month extension of time for the filing of this response. The Action was dated 03 November 2004, making the three-month response

Office Action Response
U.S.S.N. 10/073,682
Page No. 18 of 18

deadline 03 February 2005. This response is being filed on 02 March 2005.

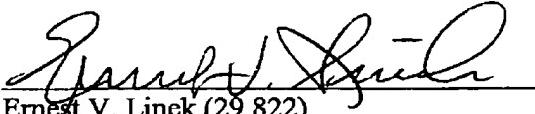
FEE AUTHORIZATION

Please charge all fees (extra claims, time extension, etc.) due in connection with this filing to Deposit Account No. 19-0733.

CERTIFICATE OF FACSIMILE TRANSMISSION

The undersigned hereby certifies that this correspondence was submitted by facsimile in the USPTO on the date shown on Page 1.

Respectfully submitted,


Ernest V. Linek (29,822)
Attorney for Applicant

Document No. 112765